REMARKS

Claims 1-22 are pending in the present application. With this response, claims 1, 8, and 20 are amended, claims 3-5, 12-19, 21, and 22 are canceled, and claims 23-24 are added. Applicants reserve the right to pursue canceled subject matter in continuing applications. Support for claims 23-24 can be found throughout the specification, see for example, paragraph [0019]. All claim amendments are made without prejudice and do not represent acquiescence in any ground of rejection.

Rejection under 35 U.S.C. § 112

Claims 1-11 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. According to the examiner, the specification does not enable any person skilled in the art to which it pertains to make and use the invention commensurate in scope with claims 1-11 and 20. Although applicants believe that the full scope of the claims is enabled, solely to expedite prosecution, applicants are amending the claims to recite that the ocular disease is one that is caused by a bacterial microbe. To the extent the rejection applies to the claims as amended, applicants respectfully traverse and request reconsideration because there is no evidence of record suggesting that a skilled practitioner would be unable to carry out the claimed methods.

The initial burden to support an enablement rejection rests on the examiner. In this regard, M.P.E.P. § 2164.04 states: "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)(examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure)." M.P.E.P. § 2164.04 further states that "a specification **must** be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)."

Viewed in this context, there is simply no reason to doubt that applicants' claimed methods are enabled. The specification on pages 19-27 provides adequate guidance on how

to prepare pharmaceutical compositions comprising collectins or surfactant proteins and how to administer them to a subject. To the extent that the examiner is requiring factual evidence showing that treatment has occurred using the specific pharmaceutical composition claimed (Office Action at pages 6-7), applicants are not aware of any requirement for such evidence. A claimed method is enabled under the patent laws so long those skilled in the art can practice it and would have no reason to doubt that it would have at least some measurable effect. Thus, any alleged absence of "testing" is irrelevant. Moreover, it is well-established that pharmaceutical inventions usually require further research and development. *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995). Were such inventions not patentable long before being optimized or ready for human use, the incentive to fully research and develop vital drugs and potential cures would be completely removed. Id. at 1567-68.

To the extent that the rejection is based on disbelief by the examiner that a collectin or surfactant protein can be used to treat a bacterial ocular disease, applicants request reconsideration. The Action provides no reason to believe that a skilled practitioner, after reading the application, would have any trouble believing that a collectin or surfactant protein can be used for the treatment of bacterial ocular disease. The example and figure sections provide *in vitro* and *in vivo* data demonstrating that the methods of the present invention can be used to treat bacterial ocular disease. Figure 5, for example, demonstrates that recombinant SP-D was able to inhibit bacterial invasion of rabbit corneal cells.

The examiner simply provides no evidence that a skilled practitioner, after reading the present specification, would be unable to prepare a pharmaceutical composition comprising a collectin or surfactant protein, administer it to a subject, and obtain some measurable effect, *i.e.,* protection of the eye from bacterial infection. Absent such evidence, the rejection for alleged lack of enablement is improper and should be withdrawn.

Applicants respectfully submit that the present application is in condition for allowance. If the examiner believes that personal communication will expedite prosecution of this application, the examiner is invited to telephone the undersigned at the number provided. Favorable consideration and an early notice of allowance are respectfully requested.

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/Leslie E. Aberman/
Leslie E. Aberman
Registration No. 54,836

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439